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[10121/01601]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : McGUCKIN, Jr.
Serial No. : 09/697,306
Filed : October 27, 2000
For : Surgical Apparatus and Method
Group Art Unit : 3761
Examiner : Glenn K. Dawson

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TRANSMITTAL

Transmitted herewith please find three (3) copies of a Supplemental Reply Brief for filing in the above-identified application. No fees are believed to be required. However, if any fees are required, please charge the Deposit Account of **Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this Transmittal is enclosed for that purpose.

Respectfully submitted,

Dated: July 25, 2005

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Sir:

SUPPLEMENTAL REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Supplemental Examiner's Answer mailed on May 24, 2005 to the decision by the Board of Patent Appeal and Interferences ("BPAI") filed April 29, 2005, and pursuant to 37 C.F.R. § 41.41, appellant presents in triplicate this supplemental reply brief in the above-captioned application.

This is an appeal to the BPAI from the Examiner's final rejection of claims 36 - 48 in the final Office Action dated November 7, 2003 as clarified in the Advisory Action mailed February 17, 2004 and further clarified in the Examiner's Answer mailed September 7, 2004. The BPAI remanded the application to the Examiner for further consideration of arguments presented by appellant in the Reply Brief filed November 4, 2004. The appealed claims are set forth in the attached Claims Appendix.

1. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 36 - 38, 40 - 44 and 46 - 48 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,395,030 to Kuramoto ("Kuramoto").
- II. Whether claims 36 - 48 are unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,389,98 to Tsuruta ("Tsuruta") in view of U.S. Patent No. 5,562, 694 to Sauer ("Sauer") and in further view of German Patent Publication No. 4,006,673 to Kessel ("Kessel").

2. Grouping of Claims

Claims 36 - 43 stand together and claims 44 - 48 stand together.

3. Argument

- I. The Rejection of Claims 36 - 38, 40 - 44 and 46 - 48 Under 35 U.S.C. § 102(e) as Anticipated by U.S. Patent No. 5,395,030 to Kuramoto ("Kuramoto") Should be Reversed.

In the decision issued by the BPAI ("the Decision"), the application was remanded with an instruction to the Examiner to consider arguments presented with respect to the rejection under 35 U.S.C. § 102(e) over Kuramoto on pages 4 and 5 of the Reply Brief filed on November 4, 2004. In the Supplemental Examiner's Answer to the Decision, the Examiner asserts that Kuramoto shows an endoscopic stapler having a capsule with a stapling mechanism and a cutter that may be inserted into the large intestine through the anus. The Examiner also states that a

forceps draws a tissue between a stapler and an anvil included in the stapling mechanism of the capsule.

Claim 36 recites a resection apparatus comprising “an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle” and *“a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue.”*

As shown in Figs. 22-24 of Kuramoto, the stapler includes a holding forceps 150 used only to manipulate and hold the tip of an anvil shaft 147. (Kuramoto, col. 16, line 53 - col. 17, line 65). That is, the sole function of the holding forceps 150 is to draw an anvil 146 toward a housing 138 to perform a stapling and a cutting operation. Kuramoto neither discloses nor suggests that the forceps 150 would be suitable in any manner for drawing tissue between the anvil 146 and the housing 138.

The Examiner contends that prior to the anvil shaft 147 piercing the tissue 114, 113, “the

forceps could be placed to extend out hole 140 to grasp section 114 of tissue to draw it into position between 138 and where the anvil will pierce through 114.” (Supplemental Examiner’s Answer, page 5). The tissue 114 is in the duodenum while the forceps 150 will exit the hole 140 facing the stomach tissue 113. Thus, it appears that the Examiner is suggesting that the forceps 150 would be extended distally and maneuvered through the stomach 110 into the duodenum 111 to the tissue 114. The forceps 150 would then grab the tissue 114 and pull it over the anvil shaft 147. Appellant maintains that Kuramoto does not disclose or suggest grasping tissue using the forceps 150, and certainly never discloses grasping and pulling tissue with enough force to pierce the tissue. For example, to pierce the tissue 114, the forceps 150 would have to pull the tissue 114 in a direction parallel to the anvil shaft 147 while being adjacent thereto such that the anvil shaft 147 will pierce the tissue 114 and not bend in the direction of the force applied by the forceps 150. Nor does Kuramoto disclose or suggest any control mechanism or steering apparatus which would allow the type of maneuvering required to position the forceps 150 adjacent to the tissue 114.

The Examiner further states that Fig. 23 of Kuramoto shows that the forceps 150 could “easily grasp another section of tissue, pull it over the pin and even cause the pin to puncture the new tissue, followed by using the forceps to grasp the pin 147 and draw the pin to the stapler.” (Supplemental Examiner’s Answer, page 5). Again, it seems that the Examiner is suggesting applications of the stapler which Kuramoto did not consider, or more importantly, intend. For example, Kuramoto never discloses that the forceps 150 does anything but grasp and pull the

anvil shaft 147. In fact, Kuramoto never even discloses that the forceps 150 could apply a distally-directed force to pierce the new thickness of tissue.

The Examiner further states that “some tissues would be thin and elastic enough to be brought into the hole 140, still grasped by the forceps jaws allowing the forceps to cause tissue to be drawn into the cutting zone...after the pin of the anvil entered hole 140.” (Supplemental Examiner’s Answer, pages 5-6). This suggestion with regard to the operation of the forceps 150 is contrary to the express disclosure of Kuramoto. With respect to Figs. 22-24, Kuramoto teaches that the forceps 150 draws the anvil shaft 147 into the hole 140 pulling the anvil 146 proximally against the housing 138 to complete the stapling and cutting operations. (Kuramoto, col. 17, lines 39-41). Thus, it is respectfully submitted that tissue can never be drawn into the hole 140, because at all times, either the forceps 150 or the anvil shaft 147 resides therein.

The Examiner maintains the argument that “the cutting zone” recited in claim 36 is shown in Kuramoto as any area adjacent to the cutter. (Supplemental Examiner’s Answer, page 6). The applicant reiterates that, because there is absolutely no showing or suggestion that would lead one skill in the art to conclude that an annular cutter 138a would be effective without the anvil 146 pressing the tissue toward the blade. Thus, the cutting zone in Kuramoto is no more than the area between the housing 138 and the anvil 146 after the anvil 146 has been coupled to the housing 138. With respect to Fig. 24, Kuramoto states, “[a]t the same time the walls 113 and 114 are stapled together, the annular cutter 138a is thrust forward, excising those parts of the walls 113 and 114 which are located inside the circular seams.” (Kuramoto, col. 17, lines 52-

56). This statement makes clear that Kuramoto only contemplates the cutting zone being the area of tissue to be excised, which is between the housing 138 and the anvil 146, after the anvil 146 has been coupled to the housing 138.

Therefore, appellant respectfully maintains the view that Kuramoto does not disclose “a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone,” as the forceps 150 is not a tissue grabber and no cutting zone is formed in Kuramoto when the housing 138 is not connected to the anvil 146.

II. The Rejection of Claims 36 - 48 Under 35 U.S.C. § 103 Over
Tsuruta In View of Sauer and Kessel Should Be Reversed

In the Supplemental Examiner’s Answer, the Examiner states that Tsuruta shows a stapling assembly which could be used in or through a bodily orifice. The Examiner further states that Sauer shows a grasper which could be combined with the stapling assembly of Tsuruta to achieve the claimed invention. Furthermore, the Examiner states that Kessel discloses forceps with an internal endoscope.

Claim 36 recites “*a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle.*” The Examiner states that the stapling assembly of Tsuruta could have been used

in or through a bodily orifice. (Supplemental Examiner's Answer, page 6). In contrast, Tsuruta expressly states that to obtain access to the body, "[a] body wall or the like is incised [and] [t]he stapling member 5 and the insertion section 2 are inserted into a body cavity through the incision." (Tsuruta, col. 10, lines 8-10). Also, in a separate embodiment of the stapling assembly, access to the abdominal cavity is made via "[a]n incision...formed in a body wall such as the abdominal wall." (Tsuruta, col. 26, lines 43-45). Even assuming the Examiner's argument to be true, Tsuruta provides no description about how to manufacture and/or operate the stapling assembly, such that the insertion section 2 extends through the body and out a natural body orifice. That is, Tsuruta does not disclose the flexible support structure and the mechanisms involved in transmitting manipulations by the user of the stapler from the control handle to the stapler along a flexible instrument - and certainly does not teach or suggest the structure necessary to arrive at a solution which would enable the device to be flexible enough to travel through a body lumen from a naturally occurring body orifice as required in claim 36. It is respectfully submitted therefore that no such flexible member extending "*through the body and out a natural body orifice to the control handle*," as recited in claim 36 is shown or suggested by Tsuruta.

Appellant maintains that Tsuruta not describe any graspers grasping tissue in conjunction with its many embodiments, and that it specifically states that its stapler allows surgeons "to gather tissues a and b, *without using forceps*." (Specification, col. 22, lines 20 - 22). In response, the Examiner states that "forceps would merely be inserted through a portion of tube 9

so that the forceps jaws could access the area between jaws 3 and 4 of the stapler.”

(Supplemental Examiner’s Answer, page 7). Initially, it should be noted that the use of forceps is neither disclosed nor suggested, and would be structurally incompatible with the stapling assembly in Tsuruta. Furthermore, there is no motivation to include such forceps as Tsuruta is specifically directed to eliminating them. As shown in Figs. 4-6, an inner tube 8 encloses only the disclosed internal components (e.g., a wire cutter 20, pusher plates 24, a hinge pin 11, etc.) and does not leave room for the forceps. Further, the wire cutter 20, the pusher plates 24 and the hinge pin 11, shown in Fig. 4, would prevent exposure of the forceps beyond a distal end of the inner tube 8. In fact, the wire cutter 20 does not enter the anvil 4 until the cartridge 3 has been closed thereon. Thus, the forceps are incompatible with Tsuruta. Even assuming the forceps could be used with Tsuruta, when drawing tissue proximally, the tissue would not be drawn between the anvil 4 and cartridge 3 due to their curvatures. That is, tissue drawn proximally would not be placed in a position to be stapled or cut, frustrating the purpose of Tsuruta.

The Examiner maintains that Sauer describes a device which discloses use of internal forceps to grasp and draw tissue into a cutting zone. Internal forceps 402 shown in Fig. 4 of Sauer are part of a second surgical grasping instrument 400 that is slidably received within a tube 38 on the surgical apparatus 10. Thus, the internal forceps 402 are not an integrated part of the surgical apparatus 10 of Sauer. As noted above, the inner tube 8 of Tsuruta does not provide space for the internal forceps 402, and the internal forceps 402 would be prevented from extending past a distal opening of the inner tube 8 by the wire cutter 8 and the hinge pin 11.

Therefore, it is respectfully submitted that one of ordinary skill in the art would not have combined the stapling assembly of Tsuruta with the second surgical grasping instrument 400 of Sauer.

The Examiner states that the inner tube 8 of Tsuruta could further include, along with the internal forceps 402 of Sauer, an endoscope as described in Kessel. With regard to the citation of Kessel, the Examiner states, "the only question at hand is whether there is motivation to place an endoscope inside the stapler with forceps combination of Tsuruta and Sauer." (Supplemental Examiner's Answer, page 8). Appellant respectfully submits that the Examiner's question must be answered in the negative, because Kessel never discloses or suggests any structures for surgical stapling and/or cutting tissue. That is, there is no motivation to combine the endoscope in Kessel with the stapling assembly in Tsuruta. Therefore, it is respectfully submitted that Tsuruta does not disclose or suggest "a coupling structure for selectively coupling to a flexible endoscope," and, as such, it would be improper to combine the teachings of Kessel with Tsuruta. It is respectfully submitted that Kessel fails to cure the above-noted deficiencies in Tsuruta and Sauer.

For these reasons, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either shows or suggests an apparatus for resecting tissue within a body lumen, comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal

tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle,” as recited in claim 36.

It is therefore respectfully submitted that claim 36 is not rendered obvious by Tsuruta, Sauer and Kessel either taken alone or in combination and that this rejection should be withdrawn. Because claims 37 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Similarly, claim 44 recites “*an operating head including a coupling structure for selectively coupling to the endoscope, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained, wherein the anvil and the stapling mechanism are permanently coupled to one another,*” in combination with “*a flexible grasping mechanism extending through the sheath for drawing tissue into a space between the stapling mechanism and the anvil.*”

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either shows or suggests a system including “*a flexible endoscope*”

and “an operating head including *a coupling structure for selectively coupling to the endoscope,*” as recited in claim 44.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Kessel either taken alone or in combination and that this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Therefore, at least for these reasons and the reasons in the previously filed Reply and Appeal Briefs, it is respectfully submitted that all of the presently pending claims are allowable. Appellant respectfully requests that the Board overturn the Examiner’s rejection of these claims.

4. Conclusions

For the reasons set forth above, the appellant respectfully requests that the Board reverse the final rejections of claims 36 - 48 by the Examiner under 35 U.S.C. §§ 102 and 103, and indicate that these claims are allowable along with currently allowed claims 49 - 51.

Respectfully submitted,

Fay, Kaplun & Marcin, L.L.P.

Date: July 22, 2005

By


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CLAIMS APPENDIX

36. An apparatus for resecting tissue within a body lumen, comprising:

an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly;

a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle; and

a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue.

37. The apparatus of claim 36, further comprising a cutting element for cutting the selected portion of tissue from the abutting portions of the grasped fold tissue fastened together by the suturing assembly.

38. The apparatus of claim 36, wherein the suturing assembly includes an anvil and a stapling mechanism movably coupled to one another for movement between a closed position and a tissue receiving position.

39. The apparatus of claim 36, wherein the endoscope is slidably received within an endoscope receiving lumen formed in the operating capsule.

40. The apparatus of claim 36, further comprising:

a flexible sheath, a distal end of which is coupled to a proximal end of the operating capsule; and

a control handle coupled to a proximal end of the sheath wherein, when the operating capsule is in an operative position within a body lumen, the control handle remains outside the body lumen.

41. The apparatus of claim 36, further comprising a control handle which, when the operating capsule is in an operative position within a body lumen, remains outside the body, and a first flexible control element extending from the control handle through the sheath to the operating head.

42. The apparatus of claim 41, wherein the first control element is a cable extending between the control handle and the suturing assembly.

43. The apparatus of claim 38, wherein the anvil and the stapling mechanism are rotatably coupled to one another for movement between the closed and tissue receiving positions.

44. A system for resecting tissue from within a body lumen, comprising:

- a flexible endoscope;

- an operating head including a coupling structure for selectively coupling to the endoscope, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained;

- a flexible sheath extending from a proximal end of the operating head so that, when the operating head is in an operative position within a body lumen, a proximal end of the flexible sheath extends out of the body lumen;

- a flexible grasping mechanism extending through the sheath for grasping a full thickness fold of tissue including a portion of tissue selected for resectioning and drawing the grasped fold of tissue into a space between the stapling mechanism and the anvil; and

- a control handle coupled to the proximal end of the flexible sheath.

45. The system of claim 44, wherein the endoscope is slidably received through a lumen extending within the operating head.
46. The system of claim 44, further comprising a first flexible control member extending within the flexible sheath between the control handle and the stapling mechanism.
47. The system of claim 45, wherein the operating head further comprises a position adjusting mechanism for adjusting the position of the anvil relative to the stapling mechanism, the system further comprising a position adjusting flexible control member extending between the control handle and the position adjusting mechanism.
48. The system of claim 47, wherein the position adjusting mechanism moves the anvil and the stapling mechanism relative to one another between the tissue receiving position and a stapling position in which the anvil and the stapling mechanism are separated by a predetermined gap, wherein the predetermined gap is smaller than a separation between the anvil and the stapling mechanism when in the tissue receiving position.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.